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Appl. No. 10/522,538

March 1, 2011

***Response to Notice of Non-Compliant Amendment mailed February 16, 2010***

**REMARKS/ARGUMENTS**

On ***December 15, 2010***, Applicant filed an Amendment in response to an Office Action mailed in this application on ***June 15, 2010***. On ***February 16, 2011***, a Notice of Non-Compliant Amendment was mailed, in which the ***December 15, 2010*** Amendment was identified as being non-compliant because a complete listing of the claims were not present. By this Corrected Amendment, previously cancelled claims 1 – 30 are now listed with the required “Canceled” identifier. It is believed that this is a complete response to the Non-Compliant Notice of ***February 16, 2011***.

Reconsideration of this application is respectfully requested. To this end, ***petition is hereby made for a (3) three-month extension of time to respond to the outstanding Office Action of June 15, 2010***. The fee for this extension is being submitted with this paper. Nevertheless, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Claims 31, 32 and 58 – 64 are pending in this application, claims 33 – 57 and 65 – 93 having been withdrawn from further consideration. Upon entry of this Amendment, claims 31, 32, 60, 63 and 64 will be amended to clarify the invention and/or to better conform them to U.S. patent practice, claims 58 – 61 will be amended to better conform them to U.S. patent practice, and claim 62 will be cancelled. In addition, new claims 94 – 101 will be added.

In making the foregoing claim amendments, Applicant notes that features from claims 58, 61, and 62 (poly-paraxylylene polymer), have been incorporated into amended claim 31, features from claims 31, 58, 61, and 62 (biocompatible metal coating) have been incorporated into new

claim 94, and new claims 95-101 correspond to previously presented claims 31, 58-61, 63 and 64.

In the outstanding Office Action, the Examiner rejected claims 31, 32 and 58-64 under 35 U.S.C. §112, second paragraph, as being indefinite because of either the inclusion of incorrect punctuation or a lack of clarity in certain terms used in the claims. In response to the claim rejections under § 112, second paragraph, claim 31 has been written in a single sentence, claim 32 has been amended to clarify that the layer or coating of claim 32 is the same layer or coating as in claim 31, claim 60 has been amended to clarify that it is the base material that comprises a polyurethane layer surrounding a silicone layer, claim 63: has been amended to clarify that the silicone is hard silicone, and claim 64 has been amended to clarify that reference is made to the layer or coating of the property improving means. In view of these amendments, it is believed that the claim rejections under § 112, second paragraph, should now be withdrawn.

In the outstanding Office Action, the Examiner also rejected, as being unpatentable under 35 U.S.C. §103(a), claims 31, 32, 58-61 and 63 over Fierro (U.S. Patent Publication No. 2002/0183588) in view of Stoy *et al.* (U.S. Patent No. 4,480,642), and claim 62 over Fierro and Stoy, as applied to claims 31, 58 and 61, and further in view of Wijeratne *et al* (U.S. Patent No. 6,287,315). The Examiner's rejections are respectfully traversed.

For a claimed invention to be obvious over a combination of references, there must have been some reason as to why one of ordinary skill in the relevant art would have combined the references to produce the claimed invention. Here, the claims of the present application are not obvious over the combination of Fierro, Stoy and Wijeratne because, even assuming, *arguendo*,

that the Examiner properly combined these references, the result would still not be the claimed invention.

In rejecting previously pending claim 62 (now part of claim 31) under 35 USC § 103, the Examiner relied on a combination of three different references. However, the Examiner has acknowledge that the combination of Fierro and Stoy does not set forth the use of the claimed material for the layer or coating property improving means. To compensate for this deficiency, the Examiner states the following:

*The property improving means of the combination is directed to friction reducing material. Wijeratne teaches low-friction material including polyurethane, silicone or PTFE (polytetrafluoroethylene) may all be substituted for one another. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use polytetrafluoroethylene in place of the material for reducing friction as set forth in the combination as a substitution of functionally equivalent materials as shown by Wijeratne. Such a substitution would produce predictable results with a high expectation of success.*

6/15/2010 Office Action, page 5.

However, Wijeratne does not disclose the use of poly-paraxylylene polymer (Parylene) or a biocompatible metal coating as a property improving means. Since these materials are not disclosed in the cited prior art, the independent claims must be considered do define non-obvious devices. For this reason alone, the claims of the present application are not obvious over the combination of Fierro, Stoy and Wijeratne.

With regard to the primary Fierro reference cited by the Examiner, independent claim 1 of the present application defines an implantable constriction device for constricting penile blood vessels of a patient for treating impotence. Independent claim 31 defines the claimed implantable constriction device as comprising a base material comprising a layer of polyurethane

and a layer of silicone. Applicant contends that this combination of materials gives unexpectedly good properties regarding fatigue resistance, *etc.*

The Examiner alleges that Fierro teaches an implantable constriction as shown in Figure 3 of Fierro. Applicant contends that this is wrong, in that Fierro teaches a sling 1 with a pad 6, the sling being used for stabilizing the urethra by means of urethral suspension. *See* Fierro, para. [0008] and [0009]. Applicant notes that, as can be seen from Figure 13 of Fierro, the neck of the bladder or the urethra 13 lays on the pad 6, which thereby permits a reduction, or even an elimination of, the friction between the sling and the neck of the bladder or the urethra. Thus, there is no restriction or constriction of the urethra, as opposed to the claimed device, which is a constriction device. Applicant contends that it must be appreciated that the technical problems associated with a constriction device and a sling are widely different.

Thus, Applicant contends that it is evident that the claimed invention, as defined by independent claim 31, is not obvious over Fierro in combination with the other cited references. And because independent claim 31 is not obvious over Fierro in combination with the other cited references, dependent claims 32, 58-61, 63 and 64 are also not obvious over Fierro in combination with the other cited references.

Finally, the Examiner provisionally rejected claims 31, 32, 58 – 64 on the ground of non-statutory, “obviousness-type” double patenting over claims 1 – 4, 8 – 12, 17 – 21, 23 – 27, 32 – 44, 53 – 60, 72 – 76 and 78 – 81 of co-pending Application No. 11/889,756. To overcome this rejection, Applicant is submitting a suitable Terminal Disclaimer.

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In view of the forgoing, it is believed that this application is now in condition for allowance, which action is earnestly solicited. If any issues remain with regard to this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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